

**WHAT IS CLAIMED IS:**

1. A prosthetic device for use in the treatment of aortic stenosis in the aortic valve of a patient's heart, said prosthetic device having a compressed state for transarterial delivery and being expandable to an expanded state for implantation, said prosthetic device comprising:

an expandable metal base constructed so as to be implantable in the expanded state of the prosthetic device in the aortic annulus of the aortic valve;

and an inner envelope lining the inner surface of the metal base;

characterized in that said inner envelope in the expanded state of the prosthetic device extends into the aorta and is of a diverging conical configuration, in which its diameter gradually increases from its proximal end within the aortic annulus to its distal end extending into the aorta, such as to produce, during systole, a non-turbulent blood flow into the aorta with pressure recovery at the distal end of the plastic envelope.

2. The prosthetic device according to Claim 1, wherein, in the expanded state of the prosthetic device, said inner envelope of diverging conical configuration has a proximal end of 5–20 mm in diameter and a distal end of 15–30 mm in diameter, and is of 15–45 mm in length.

3. The prosthetic device according to Claim 2, wherein said proximal end of the inner envelope includes a short straight section of uniform diameter within said aortic annulus effective to avoid flow separation through said plastic envelope.

4. The prosthetic device according to Claim 3, wherein said short straight section has a length of 2–10 mm.

5. The prosthetic device according to Claim 1, wherein said aortic valve of the patient's heart is of the type which includes a plurality of leaflets movable to open and closed positions and wherein said metal base includes two annular clamps engageable with the opposite sides of said leaflets in their open positions for clamping the metal base to said leaflets.

6. The prosthetic device according to Claim 5, wherein each of said two annular clamps includes an annular array of fingers.

7. The prosthetic device according to Claim 6, wherein said metal base includes an annular array of bracing elements at the distal end of the prosthetic device engageable with the inner surface of the aorta for bracing the prosthetic device within the aorta.

8. The prosthetic device according to Claim 7, wherein said bracing elements are integrally formed at one end with said annular array of fingers of one of said annular clamps.

9. The prosthetic device according to Claim 1, wherein said metal base, in the expanded state of the prosthetic device, extends to said distal end of the inner envelope, such that said inner envelope serves as a liner lining the inner surface of the metal base from said proximal end to said distal end of the prosthetic device.

10. The prosthetic device according to Claim 9, wherein said metal base at the distal end of the prosthetic device carries a prosthetic valve controlling blood flow from the heart into the aorta.

11. The prosthetic device according to Claim 10, wherein said prosthetic valve includes a plurality of leaflets movable to open and closed positions.

12. The prosthetic device according to Claim 11, wherein said leaflets of the prosthetic valve are integral with said inner envelope lining the inner surface of the metal base.

13. The prosthetic device according to Claim 1, wherein said metal base is configured and dimensioned to engage only the aortic annulus of the aortic valve when implanted therein, said inner envelope extending into the aorta being of said diverging conical configuration during systole to permit forward blood flow therethrough, but collapsing during diastole to block reverse blood-flow therethrough.

14. The prosthetic device according to Claim 13, wherein said inner envelope extending into the aorta is of a flexible pliable material.

15. The prosthetic device according to Claim 13, wherein said inner envelope extending into the aorta includes a plurality of axially-extending reinforcing struts.

16. The prosthetic device according to Claim 15, wherein said reinforcing struts are hingedly connected to said metal base.

17. A prosthetic device for implantation in an orifice formed in a wall of a body passageway, said prosthetic device having a compressed state for delivery via said body passageway to the implantation site, and being expandable to an expanded state for implantation in said orifice; said prosthetic device comprising:

an expandable metal base configured so as to be receivable in said orifice;

and two annular clamps carried by said metal base and engageable with the opposite faces of said wall in the expanded state of the metal base for clamping said metal base within said orifice.

18. The prosthetic device according to Claim 17, wherein each of said two annular clamps includes an annular array of fingers.

19. The prosthetic device according to Claim 17, wherein said prosthetic device further comprises an inner envelope lining the inner surface of said metal base; said inner envelope, in the expanded state of the prosthetic device, being of a diverging conical configuration in which its diameter gradually increases from its proximal end within said orifice, to its distal end spaced from said orifice.

20. The prosthetic device according to Claim 19, wherein, in the expanded state of the prosthetic device, said inner envelope of diverging conical configuration has a proximal end of 5–20 mm in diameter and a distal end of 15–30 mm in diameter, and is of 15–45 mm in length.

21. The prosthetic device according to Claim 20, wherein said inner envelope of diverging conical configuration also includes a short straight section of the same diameter as, and adjacent, to said proximal end.

22. The prosthetic device according to Claim 21, wherein said short straight section has a length of 2–10 mm.

23. The prosthetic device according to Claim 19, wherein said metal base, in the expanded state of the prosthetic device, extends to said distal end of the inner envelope, such that said inner envelope serves as a liner lining the inner surface of the metal base from said proximal end to said distal end of the prosthetic device.

24. The prosthetic device according to Claim 23, wherein said orifice is the aortic annulus of the aortic valve in a patient's heart; and wherein said distal end of the metal base carries a prosthetic valve controlling blood flow from the heart to the aorta.

25. The prosthetic device according to Claim 24, wherein said prosthetic valve includes a plurality of leaflets movable to an open position during systole and to a closed position during diastole.

26. The prosthetic device according to Claim 25, wherein said leaflets of the prosthetic valve are integral with said inner envelope lining the inner surface of the metal base.

27. The prosthetic device according to Claim 24, wherein said metal base includes an annular array of bracing fingers at the distal end of the prosthetic device engageable with the inner surface of the aorta for bracing the distal end of the prosthetic device within the aorta.

28. The prosthetic device according to Claim 24, wherein said metal base is configured and dimensioned to engage only the aortic annulus of the aortic valve when implanted therein, said inner envelope extending into the aorta being of said diverging conical configuration during systole to permit forward blood flow therethrough, but collapsing during diastole to block reverse blood-flow therethrough.

29. The prosthetic device according to Claim 28, wherein said inner envelope extending into the aorta is of a flexible pliable material.

30. The prosthetic device according to Claim 29, wherein said inner envelope extending into the aorta includes a plurality of axially-extending reinforcing struts.

31. The prosthetic device according to Claim 30, wherein said reinforcing struts are pivotally connected to said metal base.

32. The prosthetic device according to Claim 31, wherein said reinforcing struts are of the same material as said metal base and are pivotally connected thereto by integral hinges.

33. A method of implanting a prosthetic device according to Claim 17 in an orifice formed in a wall of a body passageway, comprising:

introducing said prosthetic device in its compressed state into a catheter having a sheath engageable with and compressing said two annular clamps;

delivering said catheter and prosthetic device via said body passageway to the implantation site, with said metal base located within said orifice, and said two annular clamps located on opposite sides of the wall formed with said orifice;

moving said sheath to one side to release for expansion one of said annular clamps, and then the other of said annular clamps;

and removing said catheter with said sheath from said body passageway, leaving the metal base implanted in said orifice with said annular clamps engaging the opposite sides of said wall.

34. The method according to Claim 33, wherein said prosthetic device, while in said compressed state by said sheath, is introduced over a balloon in said catheter, said balloon being inflated, after removal of said sheath, to expand the metal base within said orifice, said balloon being deflated to remove the catheter and the sheath from said passageway.

35. The method according to Claim 33, wherein said orifice is the aortic annulus of the aortic valve of a patient's heart.

36. The method according to Claim 35, wherein said prosthetic device carries, at its distal end, a prosthetic valve controlling blood flow from the heart into the aorta.

37. A method of implanting a prosthetic device according to Claim 17, in an orifice formed in a wall of a body passageway, comprising:

introducing said prosthetic device in its compressed state into a catheter having a first sheath engageable with one of said annular clamps for retaining it in said compressed state, and a second sheath engageable with the other of said annular clamps for retaining it in said compressed state;

delivering said catheter and prosthetic device via said body passageway to the implantation site with the metal base located within said orifice, and said two annular clamps located on opposite sides of said wall in which the orifice is formed;

moving said first sheath to one side to release said one annular clamp and to its expanded state;

moving said second sheath to the opposite side to release said second annular clamp to its expanded state;

and removing said catheter and said sheathes from said body passageway, leaving the metal base implanted in said orifice with said annular clamps engaging the opposite sides of said wall.

38. The method according to Claim 37, wherein said prosthetic device, while compressed in said compressed state by said sheath, is introduced over a balloon in said catheter, said balloon being inflated, after removal of said sheathes, to firmly press the metal base within said orifice, said balloon being deflated to remove the catheter and the sheathes from said passageway.

39. The method according to Claim 37, wherein said orifice is the aortic annulus of the aortic valve of a patient's heart, and includes leaflets movable to open and closed positions; and wherein said first annular clamp, which is expanded first, is located on the side of the metal base facing the aorta, and said second annular clamp is located on the side of the metal base facing the heart.

40. The method according to Claim 39, wherein said prosthetic device carries, at its distal end, a prosthetic valve controlling blood flow from the heart into the aorta, said prosthetic valve being compressed by said first sheath, partially expanded by said movement of the first sheath to one side before moving said second sheath, and completely expanded by further movement of said first sheath after moving said second sheath.